PATENT COOPERATION TREATY

ges. 14.3.06 CSR

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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13. März 2006
HOFFMANN • EITLE, MÜNCHEN
PATENTANWÄLTE RECHTSANWÄLTE

2813 ehl. 29.05.06/ule CSR

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(PCT Rule 71.1)

Date of mailing *(day/month/year)*	13.03.2006
Applicant's or agent's file reference 107 308 a/se	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP2005/000536	20.01.2005	20.01.2004

Applicant
SORIN GROUP DEUTSCHLAND GMBH ET AL.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:	Authorized Officer
European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Rasmussen, S Tel. +31 70 340-4595

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 107 308 a/se	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/EP2005/000536	International filing date *(day/month/year)* 20.01.2005	Priority date *(day/month/year)* 20.01.2004
International Patent Classification (IPC) or national classification and IPC A61M1/36		
Applicant SORIN GROUP DEUTSCHLAND GMBH ET AL.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 7 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *sent to the applicant and to the International Bureau)* a total of sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
16.11.2005	13.03.2006
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Villeneuve, J-M Telephone No. +31 70 340-

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2005/000536

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

   Description, Pages

   1-5 as originally filed

   Claims, Numbers

   1-11 as originally filed

   Drawings, Sheets

   1/3-3/3 as originally filed

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 1-6

because:

☒ the said international application, or the said claims Nos. 1-6 relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 1-6

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	☐	has not been furnished
	☐	does not comply with the standard
the computer readable form	☐	has not been furnished
	☐	does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	8-10
	No:	Claims	7, 11
Inventive step (IS)	Yes:	Claims	
	No:	Claims	7-11
Industrial applicability (IA)	Yes:	Claims	7-11
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (SEPARATE SHEET)

International application No. PCT/EP2005/000536

Re Item III.

Claims 1-6 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT). The subject matter of claims 1-6 is a method of therapeutic treatment of the human or animal body. The method of claims 1-6 is also regarded as chirurgical because it implies the steps of inserting at least a cannula in the circulatory system of the patient.

Re Item V.

1. The following documents are referred to in this communication; the numbering will be adhered to in the rest of the procedure:

D1: EP-A-1 374 929 (JOSTRA AG) 2 January 2004 (2004-01-02)
D2: US-6 337 049 (TAMARI Y.) 8 January 2002 (2002-01-08)
D3: US-B-6 632 189 (FALLEN ET AL.) 14 October 2003 (2003-10-14)
D4: US-B1-6 524 267 (ELGAS ROGER J. ET AL.) 25 February 2003 (2003-02-25)

2 INDEPENDENT CLAIM 7

As far as it can be understood (see Item VIII below), the subject-matter of the independent claim 7 is not new in the sense of Article 33(2) PCT, and therefore the criteria of Article 33(1) PCT are not met. The reasons are as follows:

The document D1 discloses (See figure and paragraphs 15-17, the references in parentheses applying to this document):

An apparatus for extracorporeal oxygenation of a patient's blood during cardiopulmonary bypass surgery, the apparatus comprising:

- venous line means (12) for receiving venous blood from a patient;
- bubble sensing means (10), arranged at or connected to said venous line means, for

detecting bubbles in the venous blood received from said patient;

- air filter means (11), connected to the venous line means and arranged downstream of said bubble sensing means, for separating air from blood, the air filter means comprising an air chamber for receiving air and means for diverting the air entering said air filter means into said air chamber;
- blood oxygenating means (15) for oxygenating blood after passing through the air filter means;
- arterial line means (16) for returning blood to the arterial system of said patient after the blood has been oxygenated by the blood oxygenating means;
- first pump means (14), defining a first vacuum, for pumping blood through said venous line, said air filter means, said blood oxygenating means and said arterial line means; and
- second pump means (17), defining a second vacuum, to draw air from the air chamber of said air filter means only when bubbles are detected in the venous blood by the bubble sensing means.

The subject-matter of claim 7 is therefore not new.

3 DEPENDENT CLAIMS 8-11.

3.1 As far as it can be understood (see Item VIII below), the subject-matter of dependent claim 11 is not new in the sense of Article 33(2) PCT. The reasons being the same as for claim 7 (see paragraph 3. above).

3.2 The subject-matter of the dependent claims 8, 9, 10 does not involve an inventive step in the sense of Article 33(3) PCT.

- Claim 8: the same feature is disclosed in the document D2, where it is used for the same purpose as in claim 8 (see D2, figure 1 and paragraph 62).

- Claim 9: see D3, paragraphs 50,51and figure 6.

- Claim 10: see D4, paragraph 16 and figure 1. See also paragraph 3.2 above.

Re Item VIII.

The application does not meet the requirements of Article 6 PCT, because the independent claim 7 is not clear:

The following feature in the apparatus of claim 7 relates to a method of using the apparatus rather than clearly defining the apparatus in terms of its technical features. The intended limitations are therefore not clear from this claim, contrary to the requirements of Article 6 PCT:
to draw air from the air chamber of said air filter means only when bubbles are detected in the venous blood by the bubble sensing means.
It is further not clear from the wording if this feature is indeed included in the apparatus or merely optional (compare with claim 5).

Dependent claim 10 is also unclear because it relates to a method of using the apparatus rather than clearly defining the apparatus in terms of its technical features.

Dependent claim 11 is also unclear because it cannot relate to a method and depend on claims 7-10.